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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,515	10/16/2003	Brian L. Newton	1600/162	5231
2101	7590	04/21/2006	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			MCCORKLE, MELISSA A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/687,515

Applicant(s)

NEWTON ET AL.

Examiner

Melissa A. McCorkle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Py et al (6,761,286). Py discloses a valve having an open mode to permit fluid flow and a closed mode to prevent fluid flow, the medical valve comprising a body [fig 2] forming an interior 14, a proximal port 58, a distal port 214, the interior having a fluid channel between the proximal port and the distal port, and a valving element [col 8 lin 50] within the interior of the body, the valving element controlling fluid flow between the proximal and distal ports, the valving element including a resilient member and a plug 214, the resilient member forming a fluid chamber within the interior of the body, the fluid chamber being at least a part of the fluid channel, the plug cooperating with the resilient member to provide an internal seal within the interior of the body [col 3 lines 18-60], the internal seal being spaced from the proximal port, the plug radially expanding the resilient member when the valve transitions from the closed mode to the open mode [col 2 lines 60 – col 3 line 6], the radial expansion causing the fluid chamber to have a larger volume when in the open mode than when in the closed mode [col 3 line 64-col 4 line

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19], the radial expansion also causing the fluid channel to have a larger volume when in the open mode than when in the closed mode [col 3 line 64-col 4 line 19] ;

3. wherein the resilient member forms a proximal seal at the proximal port [col 3 lines 18-62],

4. wherein the plug includes a plurality of legs that bow outwardly upon application of a distally directed force [col 4 lines 35-35];

5. wherein the plug includes a plurality of legs that normally bow outwardly [col 4 lines 35-35];

6. wherein the plug includes a plurality of legs and a leg separator to prevent contact of the legs [col 4 lines 35-35];

7. wherein the interior includes a stop, the plug longitudinally moving distally within the interior to contact the stop, the plug radially expanding the resilient member after the plug contacts the stop [fig 4 part 96];

8. wherein the plug includes a distal end, the resilient member having an open distal end, the plug distal end cooperating with the resilient member open distal end to form the internal seal, wherein the internal seal is closed when the resilient member open distal end is occluded by the plug distal end [col 3 lines 40 –63];

9. wherein the valve element is swabbable [col 4 lines 46-62, able to be swabbed which would seal the device, col 5 lines 9-17];

10. wherein the valving element includes a split plug member forming at least two portions with separable opposing faces, the opposing faces being substantially flush against each other in the closed mode [col 3 lines 40-63].


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melissa A McCorkle  
Examiner  
Art Unit 3763

  
NICHOLAS D. LUCCHESI  
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